DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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STATEMENT OF

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ASSOCIATE COMMISSIONER FOR POLICY AND PLANNING

BEFORE THE

COMMITTEE ON GOVERNMENT REFORM

U.S. HOUSE OF REPRESENTATIVES

HEARING ON

INTERNET DRUG SALES

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INTRODUCTION

Mr. Chairman and Members of the Committee, I am William K. Hubbard, Associate Commissioner for Policy and Planning at the Food and Drug Administration (FDA or the Agency). John M. Taylor, III, Associate Commissioner for Regulatory Affairs at FDA is here with me. We are pleased to have this opportunity to discuss our continuing mutual concerns about the benefits and risks of pharmaceutical sales over the Internet and what the Agency has been doing to address issues related to the sale of drugs from foreign sources.

With greater and greater frequency, consumers are using the Internet to access health related information and products. Sales of consumer products over the Internet have grown rapidly, including the sale of drugs. The growth in online drug sales by reputable pharmacies has provided significant benefits to consumers. Many managed health care organizations are searching for ways to achieve cost savings and are turning to online prescription plans as a means of providing quality service at a lower cost.

A number of online drug websites, however, present risks to purchasers and unique challenges to regulators, law enforcement officials and policy makers. FDA is concerned about the public health implications of Internet drug sales, and we are responding to these concerns as we develop and implement risk-based strategies to protect the public health. FDA monitors the Internet to evaluate the quality of products and information being offered, and we encourage consumers to remain vigilant about their purchases and to rely on reputable Internet sites.

FDA remains concerned about consumers directly purchasing foreign unapproved drugs through the Internet, because of the Agency's continued concerns that there is not sufficient information or means to assure that these products are as safe and effective as products sold within the United States. But this testimony also focuses on issues related to the purchase of prescription drugs from domestic websites. In this statement, we will discuss the advantages and risks of online drug sales, outline FDA's authority and enforcement activities in this area, and describe initiatives we are taking to better respond to the regulatory challenges we face.

In the context of prescription drug sales over the Internet, the private sector also has an important role in promoting consumer education and in providing assurances to consumers about the quality of products and services they offer. Our challenge is to make sure that the protection for consumers who purchase prescription drugs in cyberspace is just as strong as the protection consumers enjoy when they purchase drugs at their corner pharmacy. Rapid technological developments have magnified the challenges we face. As electronic commerce embraces global markets, we need to acknowledge the need to assure safety and effectiveness regardless of the jurisdiction in which a U.S. consumer resides or the location of the pharmacy.

BENEFITS OF ONLINE DRUG SALES

The Internet is rapidly transforming the way we live, work, and shop in all sectors of the economy. In the health sector, telemedicine allows people in remote areas to access the expertise of doctors in the nation's finest health centers. The Internet permits individuals to obtain extensive medical information to help them understand health issues and treatment options.

Millions of Americans used the Internet last year to find medical information, either in documentary resources or through online discussions with health professionals. Conducting research regarding health concerns is the sixth most common reason that people use the Internet, according to the market research firm, Cyber Dialogue Inc.

The sale of most consumer products over the Internet has grown rapidly in recent years, including the sale of prescription medications. Prescription drug sales over the Internet can provide tremendous benefits to consumers. These benefits are many and include:

- Access to drugs for the disabled or otherwise homebound, for whom a trip to the pharmacy can be difficult;
- The convenience of shopping 24 hours a day; and a wide selection of pharmaceutical products;
- Privacy for those who don't want to discuss their medical needs in a public place.

FDA is aware that many reputable Internet pharmacies provide consumers seeking prescription drugs with a measure of safety, privacy and convenience. They can provide detailed information on drug interactions, and may e-mail customers if the drug they ordered has been recalled, a cheaper generic version of the drug becomes available or to remind them of prescription renewals. Some also sell drugs for less than traditional "brick-and mortar" pharmacies. Hyperlinks and search programs provide online customers with written product information and references to other sources of health information more easily than in the traditional storefront. Finally, as the use of computer technology to transmit prescriptions from doctors to pharmacies expands, a reduction in prescription errors may be possible.

While online pharmaceutical sales are important for some customers, brick and mortar pharmacies can offer benefits and services that are often not available through the Internet, such as quick access to prescription drugs needed for immediate treatment. These pharmacies will undoubtedly remain an essential component in the delivery of effective health care.

In matters relating to pharmaceutical sales over the Internet, the challenge for government at both the state and Federal level is to develop and implement policies that will allow legitimate electronic commerce to flourish while continuing to assure safety and efficacy of these products. Consumers must have confidence that safeguards for online consumers are as least as protective as those at brick and mortar pharmacies.

CONCERNS ABOUT ONLINE DRUG SALES

As beneficial as this technology can be, the Internet also has created a marketplace for the sale of unapproved drugs, prescription drugs dispensed without a valid prescription, or products marketed with fraudulent health claims. Consumers may have difficulty identifying which sites sell legitimate products. As FDA considers the issues related to online drug sales, we recognize that there are various types of websites engaged in drug sales. Many sites focus on selling prescription drugs and are referred to by some as "Internet pharmacies." These sites offer for sale either FDA-approved prescription drug products, or in some cases, unapproved, illegal versions of prescription drugs. While Internet sites operated by legitimate, properly licensed pharmacies provide genuine benefits to consumers, sites that are unlicensed or otherwise

engaged in the illegal dispensing of prescription drugs pose a serious potential threat to the health and safety of American citizens. In many cases, FDA cannot provide consumers with assurance that the drugs purchased over the Internet were manufactured under current good manufacturing practice (cGMP) requirements, even if the website appears to be based in the U.S. While the increase in "Internet pharmacies" engaged in illegal sales is seen as a potent threat, FDA believes that some of the non-pharmacy sites are also harmful. We have moved aggressively against these types of sites that unlawfully offer unapproved drug products, products making fraudulent health claims, or drugs for recreational use.

Patients who buy prescription drugs from an illegitimate site are at risk of suffering adverse events, some of which can be life threatening. These risks include potential side effects from inappropriately prescribed medications, dangerous drug interactions or drug contamination. Patients are also at risk because they often don't know what they are getting when they purchase some of these drugs. Although some patients may purchase genuine product, others may unknowingly buy counterfeit copies that contain inert ingredients, legitimate drugs that are outdated and have been diverted to illegitimate resellers, or dangerous sub-potent or super-potent products that were improperly manufactured.

FDA is concerned about the proliferation of sites that substitute a simple online questionnaire for a face-to-face examination and patient supervision by a health care practitioner. According to the American Medical Association, a health care practitioner who offers a prescription for a patient he or she has never seen before, based solely on an online questionnaire, generally does not meet the appropriate medical standard of care. Four years ago, the Federation of State Medical Boards, Special Committee on Professional Conduct and Ethics found that "Prescribing of medications by physicians based solely on an electronic medical questionnaire clearly fails to meet an acceptable standard of care and is outside the bounds of professional conduct." This statement is especially important in light of the primary responsibility of states in regulating the practice of medicine. FDA is concerned that the use of such questionnaires may jeopardize the privacy of a patient's medical records, as online pharmacies may not comply with privacy practices required of entities covered by the Health Insurance Portability and Accountability Act.

The Agency is equally concerned that in some Internet transactions there is an apparent absence of any health professional/patient relationship. This is a particular concern where a patient may be using a prescription drug for the first time or where the patient may be taking other medications. FDA is concerned that the selection of prescription drug products or treatment regimens for a particular patient should be made with the advice of a licensed health care practitioner who is familiar with the patient's current health status and past medical history. In situations where a customary physician-patient relationship does not exist, the patient may be practicing what amounts to self-diagnosis. Consequently, the risk of negative outcomes such as harmful drug interactions, contraindications, allergic reactions or improper dosing is potentially magnified.

Consumers can, and should, be cautious when purchasing drugs online. There are legitimate sites that dispense drugs based on valid prescriptions. Consumers should check with their State Board of Pharmacy or the National Association of Boards of Pharmacy to see if the online pharmacy possesses a valid pharmacy license and has met state quality standards.

One means that consumers have at their disposal to protect themselves is the Verified Internet Pharmacy Practice Sites, or VIPPS system, developed by the National Association of Boards of Pharmacy (NABP) in choosing online pharmacies with which to do business. This program, which verifies the legitimacy of Internet sites dispensing prescription drugs, provides a "seal of approval" to sites that apply and meet state licensure requirements and NABP's standards. Although participation in the VIPPS program is voluntary, the Agency believes this program is an example of one that is very helpful in assuring consumers that the Internet site they are using is reputable.

USE OF THE INTERNET TO BYPASS REGULATION

The unique qualities of the Internet, including its broad reach, relative anonymity, and ease of creating new or removing old websites, pose new challenges for the enforcement of the Federal Food, Drug, and Cosmetic (FD&C) Act and state laws regulating the practice of medicine and the practice of pharmacy. FDA has found that many Internet sites are actually comprised of multiple related sites and links, thereby making investigations much more complex and resource intensive. The global nature of the Internet creates special problems for effective law enforcement. Different approaches to drug approval and marketing in foreign countries further complicate law enforcement issues for U.S. officials. FDA and other U.S. government agencies must try to work with foreign governments to share information and to develop mechanisms for cooperative law enforcement, but this is a difficult task.

FDA Authority

The types of unlawful conduct that can occur when drugs are sold over the Internet are similar to unlawful activities that occur in other contexts. Under the FD&C Act, FDA has the legal authority to take action against:

- The sale, distribution or importation of an adulterated or misbranded drug;
- The sale, distribution or importation of an unapproved new drug;
- Illegal promotion of a drug;
- The sale or dispensing of a prescription drug without a valid prescription; and
- Counterfeit drugs.

When the Internet is used for an illegal sale, FDA, working with the Department of Justice (DoJ), must establish the grounds for a case, develop the same charges, and take the same actions as it would if another sales medium, such as a storefront or a magazine, had been used. FDA has investigated and referred numerous cases for criminal prosecution and initiated civil enforcement actions against online sellers of drugs and other FDA-regulated products, particularly sellers of drugs not approved by the Agency.

State Regulation of the Practice of Medicine and Pharmacy

The states have enacted laws regulating the practice of pharmacy and the practice of medicine to protect patients from harm resulting from the use of unsafe drugs, and the improper practice of

medicine and pharmacy. Under many of these laws, to receive a prescription drug, a licensed health care practitioner who determines the appropriate treatment and issues a prescription for an FDA-approved drug generally must examine a patient. The prescription may also authorize refills. The patient then has the prescription filled by a registered pharmacist working in a licensed pharmacy that meets state standards.

Even with these Federal and state systems in place, the Internet provides ample opportunities for circumventing established safeguards. The speed, ease, and anonymity of ordering products on the Internet can attract unscrupulous sellers. Individuals not licensed to sell prescription drugs can easily create websites that appear to represent legitimate pharmacies. The fact that operators can quickly change the location and appearance of their Internet site makes enforcement all the more difficult.

State and federal safeguards are not always maintained when drugs are purchased over the Internet. A health care practitioner may not examine the consumer prior to the purchase of drugs online. A patient-doctor relationship may not be established. Unfortunately, attempts to stop some U.S. doctors and online pharmacies from issuing online prescriptions without a physical examination have not always been successful. States face many obstacles when it comes to online pharmacies. State pharmacy and medical boards have limited resources for enforcement and state regulations may not fully address the Internet context. Many states have not yet fully determined how to address the issues that arise from online prescribing.

Jurisdictional Challenges

Online drug sales pose unique challenges for regulatory and law enforcement agencies at the state, Federal and international level. Internet technology can obscure the source of the product as well as provide a degree of anonymity to those responsible for selling and shipping the product. The parties to a transaction can be dispersed geographically and usually never meet. Thus, the regulatory and enforcement issues cross state, Federal, and international jurisdictional lines.

The sale of drugs to U.S. residents via foreign websites is an extremely challenging area. Medications sold on the Internet that may be legal in foreign countries may not be approved for use in the U.S. Products not approved for sale in the U.S. often do not conform to the cGMP and quality assurance requirements in U.S. laws and regulations, and it is illegal for a foreign pharmacy to ship such drugs into the U.S. Foreign sales pose the most difficult challenge for U.S. law enforcement because the seller is not within U.S. boundaries. Although FDA may have jurisdiction over a resident in a foreign country who sells in violation of the FD&C Act to a U.S. resident, from a practical standpoint, the Agency working with DOJ has a difficult time enforcing the law against foreign sellers, when they are hard to reach and outside our borders. As a result, the Agency's efforts typically focus on requesting the foreign government to take action against the seller of the product, or asking the U.S. Customs and Border Protection (CBP) to stop the imported drug at a U.S. port-of-entry.

FDA ACTIONS TO PROTECT PUBLIC HEALTH

FDA has long been engaged in taking steps to minimize the dangers to public health posed by the sales of drugs on the Internet. In July 1999, FDA adopted, and has since been implementing, an Internet Drug Sales Action Plan, which includes five key areas of activity:

- Engaging in public outreach and education;
- Partnering with professional organizations;
- Coordinating action with state and other federal agencies;
- Cooperating internationally; and
- Enhanced enforcement tailored to the Internet environment.

Public Education

FDA's "Buying Rx Drugs Online" education program is a multi-media campaign, which is centered on FDA's website: http://www.fda.gov/oc/buyonline/default.htm, which can be accessed from FDA's home page. The website includes information for consumers, including tips and warnings on how to spot health fraud, frequently asked questions (FAQ's) and where to report suspected "rogue" sites. The page is one of the most frequently visited on FDA's website, and we are currently logging approximately 60,000 complaints a month in the mailbox.

FDA's public outreach includes FDA *Talk Papers*, articles in *FDA Consumer* magazine, and information on FDA's website to help educate consumers about safely purchasing drugs online. FDA's website also provides consumers with an opportunity to submit information to the Agency about sites that may violate the FD&C Act. Another central piece of our campaign is a brochure entitled, "Buying Prescription Medicines Online: *A Consumer Safety Guide*." The brochure was produced by the CybeRx Smart Safety Coalition, a partnership of Internet companies, trade associations, health and consumer organizations and other government agencies. The number of consumer complaints received by FDA has grown steadily with the circulation of the brochure.

Professional Outreach and Partnering

FDA continues to interact with organizations representing state regulatory and law enforcement bodies, consumers, health care practitioners and industry. These cooperative relationships include the following organizations:

- The National Association of Boards of Pharmacy
- The Federation of State Medical Boards
- The National Association of Attorneys General
- The American Medical Association
- The American Pharmaceutical Association
- The National Consumers League
- The American Society of Health-Systems Pharmacists
- The National Association of Chain Drug Stores
- The National Community Pharmacists Association
- Pharmaceutical Security Institute

Coordination with State and Federal Agencies

Several Federal agencies, as well as the states, have the authority to regulate and/or enforce U.S. laws related to the sale of drug products online. Due to the growth of potential cases involving the Internet, there are instances when working with another agency or state yields a more effective enforcement result. Working closely with the states is essential to effectively regulate the sale of drugs, as well as the sale of prescription drugs without a valid prescription over the Internet. FDA has established partnership agreements with several state bodies, including the National Association of Boards of Pharmacies and the Federation of State Medical Boards, to coordinate Federal and state activities aimed at questionable practices associated with the selling and prescribing of prescription drugs over the Internet.

FDA has increased coordination with other governmental bodies and meets regularly with other Federal agencies and state officials to share information, discuss the roles and responsibilities of the parties regarding online drug sales and identify opportunities for partnering in enforcement actions. FDA maintains strong working relationships with the Department of Justice, including the Drug Enforcement Administration (DEA) and Federal Bureau of Investigation (FBI), the U.S. Postal Inspection Service, CBP, the Office of National Drug Control and Policy (ONDCP) and other appropriate Federal and state agencies. FDA believes that cooperation among Federal agencies is particularly critical to address the sale of drugs to U.S. residents by foreign sellers.

FDA is also involved in the effort to combat an increase in the abuse of prescription drugs, which is evident in the increasing illegal sales of controlled substances on the Internet. In announcing the President's National Drug Control Strategy for 2004, ONDCP has brought together the efforts of FDA, federal substance abuse prevention and treatment agencies, and law enforcement to bear on the factors contributing to rising prescription drug abuse. The Strategy incorporates education of medical professionals and consumers, outreach to businesses involved in Internet commerce, pharmaceutical manufacturers, and pharmacies. The new program includes a range of activities designed to reduce the abuse of prescription drugs, and includes the use of web crawler/data mining technology to identify, investigate and prosecute "pill mills" -- Internet pharmacies that provide controlled substances illegally.

In conjunction with DEA, FDA will implement additional investigative efforts and enforcement actions against the illegal sale, use, or diversion of controlled substances, including those occurring over the Internet. Many of these e-pharmacies are foreign-based and expose the purchaser to potentially counterfeit, contaminated, or adulterated products.

Enhanced Enforcement

Since 1999, FDA has aggressively expanded its investigation and enforcement activities relating to Internet drug sales because we believe that illegal online drug sales pose a significant public health risk. FDA has initially focused its enforcement activities in the following areas:

- Unapproved new drugs;
- Health fraud; and
- Prescription drugs sold without a valid prescription.

FDA has increased its capability to monitor the Internet and identify sites that potentially violate the FD&C Act through the use of various search tools and by upgrading its data handling capabilities. These actions help the Agency to better understand the type and extent of unlawful conduct on the Internet and to more accurately assess whether its enforcement efforts have had an impact on illegal behavior. FDA has reviewed thousands of websites and identified hundreds involved in the sale of drug products. But this remains a daunting task and each day new sites are identified.

Since 1999, FDA has reviewed potential enforcement actions and coordinated case assignments through the use of a case assessment or "triage" team with representatives from the Office of Enforcement and OCI within the Office of Regulatory Affairs (ORA), the Center for Drug Evaluation and Research (CDER), the Office of Chief Counsel (OCC) and the Office of Policy. Under the triage process, FDA obtains leads on sites that potentially violate the FD&C Act from internal Internet monitoring activity, state, other Federal or foreign law enforcement agencies, consumers, Congress, and the press. The triage team evaluates leads and decides whether they should be pursued through a civil or criminal investigation. Priority is given to cases involving unapproved new drugs, health fraud, and prescription drugs sold without a valid prescription and products with the potential for causing serious or life-threatening reactions. The triage team makes referrals, when appropriate, to various offices within FDA for follow-up.

The triage process results in a better coordination of criminal and civil enforcement actions at the appropriate Agency components and reduces overlapping effort. This process helps to ensure that decisions are made in a timely way. The Agency seeks an appropriate balance in terms of achieving a maximum deterrent effect while taking action, if needed, to remove harmful products from the market. The team will continue to oversee Internet-related enforcement activities while they are being investigated, and will ensure that they are brought to appropriate conclusion.

OCI, working with OCC, is responsible for investigations of pharmacy sites and other Internet drug sites whose operations involve potential criminal activity. The Investigative Analysis Branch analyzes the information collected by OCI. After the suspect sites are researched, and possible violations are identified, the OCI field offices receive assignment for investigative work, which often includes undercover buys. Further investigation determines the bona fides of the pharmacy and doctor(s), and examines the relationship between the patient and doctor and the doctor and pharmacy. OCI has ongoing cooperative relationships with CBP, DEA, FBI, the Postal Inspection Service and appropriate state law enforcement and regulatory agencies, and this has enhanced their investigative capabilities with regard to Internet drug sales.

The following examples of enforcement actions taken by FDA illustrate the serious risks to the public health posed by fraudulent or illegal drug sales utilizing the Internet.

Counterfeit Contraceptive Patches

On February 4, 2004, FDA issued a warning to the public about a foreign Internet site selling counterfeit contraceptive patches. These counterfeit patches contain no active ingredients and therefore provide no protection against pregnancy. The Internet site, www.rxpharmacy.ws,

apparently is operated by American Style Products of New Delhi, India. On February 12, the Agency took action against three additional Internet sites associated with sales of the counterfeit patches -- www.usarxstore.com, www.europeanrxpharmacy.com, and www.generic.com. FDA obtained the cooperation of the U.S.-based Internet service provider (ISP) in shutting down service to these websites. FDA/OCI is working with the manufacturer and other federal agencies to further investigate the matter.

The counterfeit contraceptive patches were purported to be an FDA-approved product,. Instead, customers receive packages of patches without the active ingredient necessary to make the patches effective. Moreover, the counterfeits were sent in simple plastic zip-lock bags without identifying materials, lot numbers, expiration dating or any other labeling information needed to safely and effectively use this prescription product.

Photos contrasting the legitimate contraceptive patch with the counterfeit are displayed on FDA's website. Women who have been sent contraceptive patches lacking proper labeling or not having the appearance of the approved product as described above should not use the product and should contact their healthcare providers immediately.

These websites also sold other products that purport to be versions of FDA-approved drugs. FDA is investigating these other products as well, and we urge consumers to treat any drugs purchased from this firm as being suspect. None of these products should be considered safe or effective. Additional information about the counterfeit contraceptive patches is attached as Appendix C.

Genapharm.com

On March 9, 2004, Hadi M. Ghandour, owner of Genapharm, Inc. of Austin, Texas, pled guilty to four counts of conspiracy to introduce misbranded and unapproved new drugs into interstate commerce, counterfeiting human growth hormone, and possessing controlled drugs with intent to distribute. Ghandour admitted to engaging in a conspiracy to sell unapproved, misbranded, counterfeit and Schedule I controlled drugs from 1999 to 2001. Ghandour sold these drugs through Genapharm, Inc. and Bioscultpt Technologies, Inc., and through an Internet website, www.genapharm.com.

The drugs included:

- 1,4 Butanediol, which converts into gamma hydroxybutyric acid or GHB, a Schedule I Controlled Substance, when metabolized by the human body;
- Counterfeit human growth hormone;
- 4 Bromo-2, 5-dimethoxyphenethylamine (2CB or Nexus), a Schedule I Controlled Substance;
- BZP, which if combined with 1-(3-trifluoromethylphenyl) piperazine (TFMPP), has stimulant and hallucinogenic effects similar to 3,4-methylenedioxymethamphetamine (MDMA), or ecstasy, a Schedule I Controlled Substance; and
- Tiratricol, tri-iodothyroacetic acid (TRIAC), a potent thyroid hormone.

Two other persons involved in these offenses were previously convicted and sentenced. Ghandour faces up to five years in prison and a fine of $250,000 on each count. The

investigation was conducted by FDA/OCI and the DEA, with assistance from the Dallas District Office of the FDA and the Texas Department of Health.

Rx Clinic

On December 3, 2003, a 108-count indictment charging ten individuals and three companies with illegally selling controlled substances and other prescription drugs over the Internet was unsealed. The indictment charges that the defendants used an "online ordering process" to allow consumers to order prescription controlled substance drugs over the Internet, through such websites as "www.get-it-on.com," without ever seeing a doctor. Defendants were charged with, among other things, conspiring to unlawfully distribute Schedule III and IV controlled substances (including weight-loss drugs Bontril, Ionamin, Phentermine, Adipex, and Meridia) without a legitimate medical purpose and outside the usual course of professional practice. Defendants include Vineet (Vincent) K. Chhabra of Florida, an owner, operator, and officer of the businesses, and Sabina S. Faruqui of Florida, an officer, manager, and operator of the businesses. Also indicted were five physicians, a pharmacist, and a partner of Chhabra's who co-owned and operated some of the websites. Various defendants are charged with money laundering, and the indictment seeks forfeiture of $125 million. Several defendants are charged with violating the FD&C Act by introducing into interstate commerce misbranded prescription drugs, including Bontril, Meridia, Xenical, and Viagra.

On December 19, Marvin Brown, a physician, and Luke Coukos, a pharmacist, entered guilty pleas to charges related to this case. Brown, a retired obstetrician-gynecologist, relinquished his DEA controlled substance registration, and turned in his licenses to practice medicine in Ohio and Massachusetts. Brown pled guilty to conspiracy to dispense and distribute controlled substances, and admitted that in the course of the conspiracy he authorized more than 22,056 prescriptions for Schedule III and IV controlled substance diet drugs. Coukos pled guilty to conspiracy to dispense and distribute controlled substances and to introduce into interstate commerce prescription drugs without the prescription of a practitioner licensed by law to administer prescription drugs. Coukos admitted that he personally dispensed at least 43,066 Schedule III and IV controlled substance prescriptions, and at least 9,055 prescriptions for non-controlled prescription drugs. Coukos was sentenced on March 12 to 60 months' incarceration and a $140,318 fine.

Kwikmed

On October 1, 2002, a Federal Grand Jury in Arizona returned a 198 count indictment against Kwikmed, Inc., Cymedic Health Group, Inc., four owners of these corporations, and two physicians associated with the corporations. The indictment alleges that defendants operated Internet websites, two of which include Kwikmed.com and Cymedic.com, through which they sold prescription drugs, including Viagra, Celebrex, Xenical, and Propecia. The websites did not require a consumer to have a prescription before receiving the drugs. Instead, the customers were required to complete a questionnaire, which the website told customers would be reviewed by a physician.

Customers were charged a fee for this purported medical consultation. The indictment alleged that in the overwhelming majority of applications, no medical reviews, consultations, or physical examinations by a physician took place before drugs were shipped to customers. The defendants repackaged drugs obtained from a drug wholesaler, even though they were not a registered manufacturer or a licensed pharmacy and there was never a licensed pharmacist involved. The drugs dispensed were adulterated because of the defendants' failure to follow cGMP in packaging, holding, and labeling of the drugs.

The indictment alleged that during the course of the conspiracy the defendants and others generated sales in excess of $28 million that was billed to consumers as charges for prescription drugs, doctor consultations, and shipping. The indictment charges defendants with violations of the FD&C Act, as well as conspiracy, mail fraud, and money laundering. The charges were the result of an investigation by FDA and the U.S. Postal Inspection Service.

On October 2, 2003, William J. Clemans, a physician, pled guilty to five felonies for his involvement with these Internet websites. In his plea, Clemans admitted that generally a physician did not review questionnaires before drugs were shipped to customers. Charges to which Clemans pled included: 1) conspiracy, 2) introduction of misbranded drugs into interstate commerce, 3) failure to register a drug manufacturer, 4) mail fraud, and 5) conspiracy to commit money laundering. Clemans also agreed to forfeit $600,000.

On December 16, 2003, Adalberto Robles Guzman, a physician also charged in this case, entered a guilty plea to two felony counts for tax evasion. In the plea agreement, Robles admitted he omitted from his tax return over $100,000 of income received from Kwikmed. A third defendant, Janice Gamblin, one of the owners of Kwikmed, Inc., pled guilty this month to conspiracy, introduction of misbranded drugs into interstate commerce, mail fraud, money laundering and failure to register an establishment in which drugs are manufactured; prepared; propagated; compounded; and processed.

Norfolk Men's Clinic

On February 16, 2002, a federal jury in Alabama convicted Anton Pusztai and Anita Yates of charges arising out of the operation of an online pharmacy that illegally sold prescription drugs over the Internet to consumers. On June 18, 2002, Pusztai and Yates were sentenced respectively to more than 15 and 6.5 years in prison. Pusztai, an Australian citizen, and Yates, a resident of Clanton, Alabama, were convicted of conspiracy to commit violations of the FD&C Act, conspiracy to commit money laundering, mail fraud, dispensing misbranded drugs, and operating a drug repackaging facility not registered with FDA.

From fall 1998 to the summer of 2000, the defendants operated a website called Viagra.au.com, also known as Norfolk Men's Clinic, and related sites, that sold a variety of prescription medications. The case has been appealed to the Eleventh Circuit and is awaiting a decision. This case was investigated by FDA/OCI with assistance from State and local law enforcement.

Storefront Pharmacies

FDA has taken recent actions against so-called "storefront pharmacies," which are generally walk-in businesses, sometimes associated with Internet sites, which assist U.S. consumers in ordering prescription drugs from Canadian or other foreign pharmacies and facilitate the filling of these orders. FDA is concerned about these domestic operations that are not properly licensed under state pharmacy laws, and expose consumers to a number of potential risks. As of November 2003, twenty-two states have taken, or are prepared to take, regulatory actions against storefront pharmacies that facilitate illegal imports of prescription drugs from Canada.

Rx Depot Inc.

The Department of Justice and FDA filed an injunction on September 11, 2003, to stop Rx Depot Inc. from causing the importation of prescription drugs from Canada in violation of U.S. law. The Agency brought the suit because the storefront chain posed a risk to public health by importing unapproved prescription drugs and drugs that may only be imported by the U.S. manufacturer. Earlier in the year, FDA issued a warning letter to Rx Depot in conjunction with the Arkansas State Board of Pharmacy, but the company's response was inadequate. These drugs posed a public health risk because they do not have the same assurance of safety and efficacy as drugs regulated by FDA. Rx Depot and similar companies have incorrectly stated that FDA condones their activities and that their prescription medications are "FDA approved."

On November 6, 2003, U.S. District Judge Claire Eagen granted the government's motion for a preliminary injunction and ordered Rx Depot to stop importing drugs and stop advertising and promoting any service that causes or facilitates drug imports. FDA, and the District Court Judge, concluded that operations such as Rx Depot expose the public to significant potential risks associated with unregulated imported prescription medicines.

CanaRx

On September 16, 2003, FDA issued a warning letter to CanaRx notifying the firm of our concerns about supplying prescription drugs from unregulated sources and making unwarranted claims about these products. Specifically, FDA's warning letter stated that CanaRx runs an Internet website and mail operation that illegally causes the shipment of prescription drugs from a Canadian pharmacy into the U.S., thereby exposing U.S. consumers to risky imported drug products. This potential risk is compounded by the fact that CanaRx makes misleading assurances to consumers about the safety of its drugs.

An FDA investigation of this firm showed that CanaRx operates a drug purchasing arrangement that channels drugs through companies that are not U.S. licensed pharmacies and does not consistently use shipping practices necessary to ensure its drugs are safe and effective. For example, FDA has evidence demonstrating that CanaRx shipped insulin, a product that should be stored under refrigerated conditions, in a manner that did not satisfy the storage conditions specified in FDA approved labeling, which could genuinely compromise the safety and

effectiveness of the insulin. CanaRx's response to the Agency's warning letter was inadequate, and on November 6, 2003, FDA sent a second letter reiterating our concerns about the potential safety of the product, and the firm's business practices. The investigation is ongoing.

Expedite-Rx, SPC Global Technologies, and Employer Health Options

On January 22, 2004, FDA issued a warning letter to Expedite-Rx, a technological interface, SPC Global Technologies, Ltd., a pharmacy benefits manager, and Employer Health Options, Inc., a pharmacy benefits manager, all of Temple, Texas, notifying them that it considers their drug import program to be illegal and a risk to public health. The letter accuses the firms of facilitating illegal imports of prescription drugs from Canada and misleading the public about the drugs' safety. Expedite-Rx, which does not hold a Texas Pharmacy license, was directed by the Texas State Board of Pharmacy last July to "immediately discontinue receiving/processing prescription drug orders." FDA has reviewed the three firms' responses to the Warning Letter and has requested further information from those firms.

Internet Sales Facilitators

Last fall, the popular Internet search engines Google and Yahoo, as well as Microsoft's MSN website announced that they will stop accepting advertising from unlicensed pharmacies. America Online Inc. has said it has restricted sales of illegal drugs beginning approximately two years ago.

Increasingly over the last few years, search engines have become cluttered with links to rogue Web sites. Consumers merely type in a drug name and are linked to an array of Web sites selling prescription drugs, including controlled substances. Unlicensed pharmacies selling narcotics and other prescription drugs pay Internet search engines to link their advertisements to keywords typed in by those who use the search engines. Many of these drug sellers are located offshore and many sell prescription drugs without a valid prescription.

The Agency has strongly encouraged online search engines and other advertising outlets to assist in identifying and removing access to illegitimate pharmacies. The Agency has been in contact with search engines to provide information and assist them in understanding the effect on public health of accepting such advertising.

As these actions indicate, FDA intends to work closely with its partners in the individual states in support of their efforts to curtail illegal and potentially dangerous operations, especially when they involve misleading claims about drug safety. FDA has been working closely with states and private sector entities like the online search engines to address the problem of illegal Internet pharmacy issues over the past four years to protect the public health.

CONCLUSION

Mr. Chairman, online shopping for pharmaceutical products clearly provides many benefits for consumers, but it also poses a number of serious potential risks. The nature of Internet technology presents law enforcement and policy makers with unique challenges. FDA is

grappling with these challenges, and we must strive to carefully balance consumer access to information and products with protecting the public health. We are aggressively using our existing educational, compliance and enforcement tools to combat the proliferation of unsafe or fraudulent pharmaceuticals on the Internet, and we will continue to evaluate what changes in our procedures, regulations, or the law might be appropriate to enhance our efforts. Our goal is to ensure that the protections afforded to consumers who purchase drugs from their corner drugstore also extend to consumers in the electronic marketplace.

We want to work with you and other members and committees that have an interest in this important issue, and I would be happy to answer any questions you may have.